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Clinical pharmacists' role in identification of drug related problems in a tertiary care teaching hospital in Kadapa

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Abstract:
Back ground: *A Drug-Related Problem is an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes. When reviewing a patient's drug therapy, one of the main objectives of Clinical Pharmacist are to identify systematic review of each drug order on the patient's medication charts for its appropriateness and resolve any drug-related problems.*
Aim: *To conduct a study on the identification of the drug related problems by Clinical Pharmacist.*
Method: *A Prospective observational study was conducted for a period of 6 months and then patients were categorized according to their disease condition. Adverse drug reactions were identified and classified according to Naranjo's scale. Other drug related problems were analyzed from the prescription and referred from standard literature.*
Results: *In our study we screened 508 cases for DRP's. ADR's had been manifested in 34 patients in I.P and 8 patients in O.P. Possible drug-drug interactions were found 415 in IPD and 88 in OPD. These are the maximum DRP's were identified during the study period.*
Conclusion: *In our study major drug related problems identified were adverse drug reactions. The incidence of adverse drug reaction is 0.082. About 6% of the patients were affected by adverse drug reactions.*
Keywords: *Adverse drug reaction, Clinical Pharmacist, Drug related Problems, Drug- Drug Interactions, Naranjo's causality assessment.*

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I. Introduction

A Drug-Related Problem is an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes [1]. When reviewing a patient's drug therapy, one of the main objectives of Clinical Pharmacist is to identify systematic review of each drug order on the patient's medication chart for its appropriateness and resolve any drug-related problems Eight categories of drug-related problems (DRP's) were outlined by Charles Hepler and Linda Strand in their landmark paper in 1990.They are Adverse drug reactions , Drug interactions, Untreated indication, Improper drug selection, Sub therapeutic dose, Over dosage, Failure to receive drugs, Drug use without indication [2].

DRPs can lead to ineffective pharmacotherapy and may cause drug-related morbidity and mortality. Most DRPs are avoidable and clinical pharmacists are assuming an active role in preventing and solving DRPs These problems could be well prevented or minimized by initiating changes in the drug therapy through clinical pharmacy services. Interventions in prescribing by the pharmacist can be done in following ways: Active campaigns, Reactive interventions, Passive interventions [3, 4].

II. Materials and Methods

A Prospective observational study was conducted in a South Indian tertiary care teaching hospital for a period of 6 months after Institutional Ethics Committee approvals. Patients on multiple drug therapy: with a minimum of two drugs, Patients of both sexes were recruited; Patients with intentional or accidental poisoning with the drug were excluded.

2.1 Data collection

The required information was collected in patient data collection Proforma. During the study, patient case records were received and patient demography, admitting diagnosis, past medical and medication history, physician medication order sheet and other special findings were collected.

2.2 Study procedure

The patients were prospectively selected for the study by simple random sampling method, from both IP and OP General Medicine Department. The patients were categorized male and female. Further the patients are classified according to their age group. Then patients were categorized according to their disease condition. Then the drugs in the prescription were classified according to the pharmacological classification. Adverse drug reactions were identified according to the manifestations on the patients and were notified and reported to the physician and were documented in ADR form, these ADR were classified according to Naranjo's scale. The PDDI's were identified from published information from micromedex, BNF and drugs.com. The severities of PDDI's were also identified. Other drug related problems like untreated indication, improper drug selection, sub therapeutic dose, drug use without indication, over dosage and failure to receive drugs were analyzed from the prescription and referred from standard literature.

2.3 Statistical analysis:

Mode of analysis is "Spearman Correlation". Test was performed to calculate p value for the purpose of comparison of result by using software namely "Graph Pad Prism".

III. Results

A total of 508 patients were recruited under inclusion criteria. Among them 260 belongs to Inpatient department and 248 outpatient department.

3.1. Demographics

In our study we screened 508 cases for drug related problems based up on Charles Hepler and Linda Strand classification. Out of 508 patients 255(50.2%) were male and 253 were female [Table 1].

Out of 508 patients, 70(13.9%) patients were found between the age group of 20-30, 90 (17.7%) were in between 30-40, 87 (17.12%) were in between 40-50 , 115 (22.63%) were in between 50-60, 105 (20.63%) were in between 60-70, 34 (6.69%) were in between 70-80 and 7 (1.37%) were in between 80-90 [Table 2].

3.2 Adverse drug reactions

In 508 patients 42 patients were developed adverse drug reactions.

3.2.1 Causality assessment

Suspected adverse drug reactions were assessed to establish the extent of relationship between the suspected drugs and adverse drug reactions manifested by using Naranjo's Causality Assessment scale. According to the Naranjo's algorithm majority of the reported adverse drug reactions were rated as possible 33 (78.5%), followed by probable 9 (21.5%) [Table 3].

3.2.2 Adverse drug reactions based on the therapeutic class of the drugs

Therapeutic group of the drugs associated with the adverse drug reactions is shown in. The results shows that antibiotics, 15 (35.7%) were the drug class mostly reported for adverse drug reactions followed by anti-hypertensive's, (23.8 %) [Table 4].

3.2.3 Organ system affected due to Adr's:

Gastrointestinal system 20 (47.7%) was the most commonly affected organ system followed by Nervous System 16 (38.0%) [Table 5].

3.3 Possible drug-drug interactions

The possible drug-drug interactions were found from the published information from drug information sources like micromedex, drugs.com, BNF.

3.3.1 Examples of possible drug-drug interactions which was observed during the study

There are 15 possible drug-drug interactions which were observed during the study [Table 6].

3.3.2 Severity level:

According to the severity scale, among the drug-drug interactions identified moderate interactions were found to be maximum 245(48.8%), followed by minor 143(28.4%), major115 (22.8%) [Table 7].

3.4 Based on nature and frequency of drug related problems in I.P & O.P

Adverse drug reactions had been manifested in 34 patients in I.P and 8 patients in O.P. Possible drug-drug interactions were found 415 in inpatient department and 88 in outpatient department. These are the maximum drug related problems were identified during the study period [Table 8].

3.5 statistical analysis of drug related problems in Patients of both IP and OP

By using spearman's correlation test significant difference was found to be $P<0.0001$ between the drug related problems of inpatient and outpatient of general Medicine department.

IV. Discussion

In our study we have recruited 508 subjects of which males constitute 255 (50.2%) and females 253 (49.8%). According to the age group categorization, the patients in the age group of 50-60 were found to be maximum (22.6%) following 60-70 age group (20.6%). Of the drug related problems identified in our study, 42 persons had experienced adverse drug reactions (6.4%). Females were mostly affected by the adverse drug reactions (26 in number and 61.9%). Our study had been supported by "Jhan. et al. adverse drug reaction reporting in a pharmacovigilance center of Nepal (2012)" , Where they have reported that 55.35% of the ADRs had occurred in female patients [5].

As regards to age wise categorization, 14 (33.4%) Adverse drug reactions had occurred in the geriatric people of age group of 60-70, followed by 8 (19.0%) in the age group of 30-40, followed by 5 (10.7%) in the age group of 50-60. The older adults are vulnerable to age related physiological changes which may alter the pharmacokinetic and pharmacodynamics properties of medications and often they have multiple co-morbidities and are prescribed with multiple medications. This view was proposed by "Ding Cheng Chan et al. in their drug related problems (DRP's) identified from geriatric medication safety review clinics" (2012) [6].

Based on the Naranjo's causality assessment of the Adverse Reaction reported, 33 (78.5%) ADRs were coming in the category of possible. This is in contrast to the observation done by "Koneru r et al. in their drug-related hospitalizations at a tertiary level hospital in Bangalore: a prospective study (2008)" where they had reported that 58% patients were definite. [7] Our study also provides a contrast view as proposed by "Singhal Rohit et al in their reporting and monitoring of adverse drug reactions with cardiac drugs (2011)" where they have reported that 64.5% ADRs were probable and 32.4% ADRs were possible. [8] ADRs reported among drug classes includes Antibiotics which were found to be highest 15 (35.7%) followed by Anti-hypertensive's 10 (23.8%) and followed by anti-platelets 7 (16.6%). Our study was supported by Jhan. et al. adverse drug reaction reporting in a pharmacovigilance centre of Nepal (2012)" where they reported antimicrobials were the classes of drugs causing highest number of ADRS followed by anti-hypertensive. The incidence rate of adverse drug reaction was estimated to be 0.082. In our study GI system was found to be the organ system affected by ADR (20, 47.7%), followed by nervous system (16, 38.0%) [5].

A total of 503 drug-drug interactions were identified. Among those moderate drug-drug interactions was found to be maximum (245, 48.8%) followed by minor (143, 28.4%) and major (115, 22.8%). In this category our study was found to be in agreement with "Virendra k. Patel et al. potential drug interactions in patients admitted to cardiology wards of a south Indian teaching hospital (2011)" where they have reported a similar findings of which comparing the nature and frequency of DRPs. [9] Most of the DRPs occurred in the IP compared to OP Department. Of the DRPs to be prominent are ADR (6.4%), possible drug-drug interactions (76.7%), untreated indication (6.7%) and failure to receive therapy (5.1%). In this category our study is in contrast of the findings of "Harminder Singh et al. the incidence and nature of drug related hospital admission: a 6 month observational study in a tertiary health care hospital (2012)" in many aspects [10].

V. Conclusion

The major drug related problems identified from our study were adverse drug reactions where female patients were more susceptible. The incidence of adverse drug reaction is 0.082. About 6% of the patients were affected by adverse drug reactions. The possible drug-drug interaction was found to be more common with the female patients and geriatric patients. Comparatively Inpatient department has more DRPs than Outpatient Department. Two patients from our study had experienced severe risk associated with DRP.

Clinical pharmacists are the upcoming breed of pharmacists in our country. Clinical pharmacists can contribute improved patient outcomes by monitoring the drug therapy and can also promote rational use of drugs. Clinical pharmacists can provide reactive intervention involving in the patient care and also can offer services like drug information to the other members of the health care team so that effective therapeutic decision can be made. In this scenario we want to make a suggestion that the nursery of clinical pharmacists, the Pharm.D programme which had been introduced in our country has to be properly groomed. These budding pharmacists could offer effective patient care by means of their intervention in pharmaceutical care and hence improved therapeutic outcome could be reached.

Tables

Table 1: Patient Distribution Based On Gender

	Total Number of subjects *n=508*	
Gender	**Male**	**Female**
	255(50.2%)	253(49.8%)

Table 2: Patient Categorization Based On Age

Age group	Male	Female	Total	Percentage
20-30	36	34	70	13.9%
30-40	37	53	90	17.7%
40-50	44	43	87	17.3%
50-60	67	48	115	22.6%
60-70	53	52	105	20.6%
70-80	17	17	34	6.6%
80-90	1	6	7	1.3%
Total	255	253	508	100%

Table 3: Naranjo's Causality Assessment for the Adverse Drug Reactions Reported

Causality	No. of ADRs	Percentage
Probable	9	21.5%
Possible	33	78.5%
Definite	0	0%
Unlikely	0	0%
Total	**42**	**100%**

Table 4: Number of Adverse Drug Reactions Reported Among the Drug Classes

Class of Drug	No. of ADRs (%)
Anti-biotics	15(35.7%)
Anti-hypertensive's	10(23.8%)
Anti-platelet	7(16.6%)
Anti-viral	5(11.9%)
Anti-consultants	3(7.1%)
Anti- anginal agents	5(11.9%)
Anti-emetics	3(7.1%)
Anti-histamines	2(4.7%)
Ant-tubercular	3(7.1%)
Anti-ulceratives	15(35.7%)
Lipid lowering agents	3(7.1%)
Diuretics	1(2.3%)
Bronchodilators	1(2.3%)

Table 5: Organ System Affected Due To Adverse drug Reaction

System Affected	No. of Reaction	Percentage (%)
Nervous system	16	38.0%
Gastrointestinal system	20	47.7%
Respiratory system	1	2.4%
Dermatology	5	11.9%
Total	**42**	**100**

Table 6: Examples of Possible Drug-Drug Interactions Which Was Observed During the Study

DRUGS	INTERACTION
Amlodipine + Clopidogrel	Concurrent use of Amlodipine and Clopidogrel may result in decreased anti platelet effect and increased risk of thrombotic events
Enalapril+ Losartan	Concurrent use of angiotensin converting enzyme inhibitors and angiotensin ii receptor blockers may result in increased risk of adverse events (i.e., hypotension, syncope, hyperkalemia, changes in renal function, acute renal failure).
Aspirin+ Heparin	Concurrent use of aspirin and heparin may result in an Increased risk of bleeding
Ciprofloxacin+ Ondansetron	Concurrent use of ciprofloxacin and Ondansetron may result in an increased risk of qt

	interval prolongation.
Digoxin +Spironolactone	Concurrent use of digoxin and Spironolactone may result in digoxin toxicity (nausea, vomiting, cardiac arrhythmias).
Aspirin + Clopidogrel	Concurrent use of aspirin and clopidogrel hydrogen sulfate may result in an increased risk of bleeding.
Clopidrogel+ Atorvastatin	Atorvastatin may interfere with how Clopidrogel becomes activated in the body. If this happens, Clopidrogel may not work as effectively
Digoxin + Furosemide	Increased cardiac toxicity with cardiac glycosides if hypokalemia occurs with Diuretics.
Azithromycin + Ciprofloxacin	Concurrent Use Of Azithromycin And Ciprofloxacin May Result In An Increased Risk Of Qt Interval Prolongation
Ciprofloxacin + Haloperidol	Concurrent use of ciprofloxacin and haloperidol may result in an increased risk of qt interval prolongation.
Amlodipine + Atenolol	Concurrent Use Of Dihydropyridine Calcium Channel Blockers And Beta-Adrenergic Blockers May Result In Hypotension And /Or Bradycardia
Digoxin+ Calcium	Concurrent use of calcium and Digoxin may result in a serious risk of arrhythmia and cardiovascular collapse.
Clopidrogel+ Pantoprazole	Pantoprazole may decrease the formation of the active form of clopidogrel by slowing the conversion process.
Digoxin+ Furosemide	Increased cardiac toxicity with cardiac glycosides if hypokalemia occurs with Diuretics
Carbamazepine + Alprazolam	Carbamazepine will decrease the level or effect of Alprazolam by affecting hepatic/intestinal enzyme CYP3A4 metabolism.

Table 7: Based On Severity Scale

Severity of Interaction	No. of Interactions identified	Percentage (%)
Minor	143	28.4%
Moderate	245	48.8%
Major	115	22.8%
Total	**503**	**100%**

Table 8: Based On Nature and Frequency of Drug Related Problems in I.P and O.P

Drug related problems	No. of problems identified		
	I.P	O.P	Total
Adverse drug reactions	34	8	42(6.4%)
Possible drug-drug interactions	415	88	503(76.7%)
Untreated indications	35	9	44(6.7%)
Improper drug selections	15	5	20(3.1%)
Sub therapeutic dose	0	0	0(0%)
Over dose	4	0	4(0.6%)
Failure to receive therapy	28	5	33(5.1%)
Drug use without indication	7	2	9(1.4%)
Total	**538(82.13%)**	**117(17.87%)**	**655(100%)**

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